IN	THE	UNITED	STATES	<b>DISTRICT</b>	COURT
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### FOR THE NORTHERN DISTRICT OF CALIFORNIA

EDWARDS LIFESCIENCES LLC, et. al,

Plaintiffs,

No. C 03-03817 JSW

v.

COOK INCORPORATED, et. al,

Defendants,

ORDER DENYING W.L. GORE & ASSOCIATES, INC. MOTION FOR LEAVE TO FILE AN AMENDED ANSWER TO PLAINTIFFS' SECOND AMENDED COMPLAINT

### **INTRODUCTION**

This matter comes before the Court upon consideration of the motion for leave to file an amended answer to Plaintiffs' Second Amended Complaint filed by Defendant W.L. Gore & Associates, Inc. ("Gore"). Having considered the parties' papers, relevant legal authority, the record in this case, and having had the benefit of oral argument, the Court HEREBY DENIES Gore's motion.

## FACTUAL AND PROCEDURAL BACKGROUND

On August 15, 2003, Plaintiffs Edwards Lifesciences LLC ("Edwards") and Endogad Research PTY Limited ("Endogad") (collectively "Plaintiffs") filed this suit alleging that Defendants, Cook Incorporated ("Cook") and Gore, infringe upon U.S. Patent Nos. 6,582,458 ("the '458 Patent"), 6,613,073 ("the '073 Patent"), 6,685,736 ("the '736 Patent"), and 6,689,158

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("the '158 Patent") (collectively the "patents-in-suit"). Plaintiffs filed a First Amended Complaint on September 2, 2003. This case was stayed on November 1, 2004, pending the resolution of *Medtronic*, *Inc. v. Geoffrey White*, N.D. Civ. No. 04-2201, which was related to the above captioned matter by order dated June 9, 2004 ("the White litigation"). The Court lifted the stay on March 31, 2006. Plaintiffs filed a Second Amended Complaint on May 11, 2006. Gore filed its Answer to the Second Amended Complaint on June 23, 2006. On May 15, 2006, the parties re-commenced fact discovery, which closed on February 29, 2008. No trial date has been set.

The patents-in-suit relate to devices for treating aneurysms, in particular abdominal aortic aneurysms and occlusive disease, without resort to "open" surgery. Dr. Geoffrey White ("Dr. White") and Dr. Weiyun Yu ("Dr. Yu"), the inventors, assigned or licensed the patents-insuit to Plaintiffs. Gore claims that Dr. White or Dr. Yu, or both, had knowledge of Dr. Juan Carlos Parodi's ("Dr. Parodi") prior art in the field of stent grafts, prior art which Gore contends is material to the patents-in-suit. (Proposed Second Amended Answer to the Second Amended Complaint ("PSAA") ¶ 50.) In particular, Gore asserts that Dr. White and/or Dr. Yu knew of Dr. Parodi's article Endoluminal Aortic Aneurysm Repair Using A Balloon-Expandable Stent-Graft Device: A Progress Report, 8 ANNALS OF VASCUALAR SURGERY, Nov. 1994 and/or the book chapter Endovascular Repair of Abdominal Aortic Aneurysms, in ADVANCES IN VASCULAR SURGERY (Mosby-Year Book, 1993). (Id. ¶¶ 50, 52.) Additionally, Gore asserts Dr. White and Dr. Yu were aware of Dr. Michael Dake's ("Dr. Dake") prior art. (Id. ¶ 64.) Gore now moves to add a counterclaim for invalidity based on inequitable conduct. This claim arises from the inventors' alleged failure to disclose the above mentioned prior art to the United States Patent and Trademark Office ("PTO").

Drs. Yu and White were deposed on several occasions. Drs. White and Yu were not deposed for all purposes until February 27-29, 2008. Discovery originally was limited to ownership and, later, to matters relevant to claim construction. However, in depositions held in June 2004, Gore's counsel questioned Drs. Yu and White about their knowledge of the

publications by Dr. Parodi, on which now Gore bases its claim for inequitable conduct. In addition, in November 2007 and December 2007, Gore deposed three prosecuting attorneys for the patents-in-suit: Bruce Center, Raymond Sun, and Richard A. Neifeld (collectively the "Prosecuting Attorneys"). In all three of the Prosecuting Attorneys' depositions Gore's counsel asked about their knowledge of Dr. Parodi's published work.

### **ANALYSIS**

#### Legal Standard. A.

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Federal Rule of Civil Procedure 15(a) permits a party to amend its pleading once as a matter of right at any time before a responsive pleading is served. Once a responsive pleading has been served, however, amendment requires written consent of the adverse party or leave of the court, and leave "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). Though the decision to grant or deny the motion for leave to amend is governed by the district court's discretion, the general rule is that amendment of the pleadings is to be permitted. See Forman v. Davis, 371 U.S. 178, 230 (1962); DCD Programs, Ltd. v. Leighton, 833 F.2d 183, 186 (9th Cir. 1986). The four factors commonly used to determine the "propriety of a motion for leave to amend ... are: bad faith, undue delay, prejudice to the opposing party, and futility of amendment." DCD Programs, Ltd., 833 F.2d at 186. "These factors, however, are not of equal weight in that delay, by itself, is insufficient to justify denial of leave to amend." *Id.* The other factors used to determine the propriety of a motion for leave to amend could each, independently, support a denial of leave to amend a pleading. Lockheed Martin Corp. v. Network Solutions, Inc., 194 F.3d 980, 986 (9th Cir. 1999.) Of these factors, "prejudice to the opposing party is the most important factor." Jackson v. Bank of Hawaii, 902 F.2d 1385, 1387 (9th Cir. 1990).

### В. The Factors Favor Denying Gore's Motion for Leave to File an Amended Answer.

#### 1. **Undue Delay.**

Gore unduly delayed filing its motion for leave to amend. Courts do not look favorably upon the assertion of new legal theories, when the factual basis of those legal theories was

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known to the party for a significant amount of time prior to filing a motion for leave to amend. See, e.g., Acri v. International Ass'n of Machinists & Aerospace Workers, 781 F.2d 1393, 1398 (9th Cir. 1986) (holding that "late amendments to assert new theories are not reviewed favorably when the facts and the theory have been known to the party seeking amendment since the inception of the cause of action"). An inequitable conduct claim includes three elements: "(1) intent to deceive, (2) materiality, and (3) the misrepresentations's relationship to the targeted patent or patents." Collaboration Properties, Inc. v. Tandberg ASA, 2007 U.S. Dist. LEXIS 8632, at \*13-14 (N.D. Cal. Jan. 25, 2007). In Chodos v. West Publishing Co., 292 F.3d 992 (9th Cir. 2002), the court denied a motion for leave to amend because the "new' facts had been available to Chodos even before the first amendment to his complaint." Chodos, 292 F.3d at 1003. Here, it is undisputed that Gore had knowledge of facts regarding two of the three elements of the claim as early as 2003. Thus, like the *Chodos* case, the majority of the facts for the inequitable conduct claim were known to Gore even before its previous answer. To avoid undue delay, Gore should have properly pleaded the claim earlier in litigation.

A party that contends it learned "new" facts to support a claim should not assert a claim that it could have pleaded in previous pleadings. See, e.g., Chodos, 292 F.3d at 1003 (amending the pleading caused undue delay when the party knew of the factual basis for the amendment prior to a previous amendment). "While it is true that, with respect to inequitable conduct, 'intent may be inferred from the surrounding circumstances,' Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997), there is a difference between what [defendant] must show to prove inequitable conduct and what [defendant] must allege to plead inequitable conduct." Collaboration Properties, Inc., 2007 U.S. Dist. LEXIS 8632, at \*13-14 (emphasis in original). A claim for inequitable conduct can be made "if the party believes it can later prove that [the applicant] intended to deceive the PTO-- whether through direct or circumstantial evidence-- [the] pleading should, at the very least, reflect that belief." Id. at 14 (citations omitted). Gore represents it lacked facts to prove the intent to deceive element of the inequitable conduct claim. The "new" facts Gore relies on are from depositions of the

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Prosecuting Attorneys in November 2007. A review of the proposed counterclaim suggests Gore could have pleaded intent to deceive on information and belief prior to the Prosecuting Attorneys' depositions. While the Court appreciates Gore's hesitance to plead inequitable conduct, this "new" evidence is an unpersuasive reason for the delay associated with the proposed amendment. In conclusion, Gore presents no reason for its undue delay in amending its answer to include the claim of inequitable conduct and the Court finds this factor weighs against granting Gore's motion to amend. See Lockheed Martin Corp., 194 F.3d at 986 (9th Cir. 1999.)

#### 2. **Prejudice to Opposing Parties.**

The second factor to consider is the potential prejudice to Plaintiffs. When "additional discovery would have to be undertaken" because the amended pleading contains "different legal theories and require[s] proof of different fact[s]," the opposing party may be prejudiced. Jackson, 902 F.2d at 1387. For example, "a need to reopen discovery and therefore delay proceedings supports a district court's finding of prejudice from a delayed motion to amend the complaint." Lockheed Martin Corp., 194 F.3d at 986.

Gore's addition of an inequitable conduct claim late in this litigation prejudices Plaintiffs, because it will require additional fact discovery. Because fact discovery closed in February 2008, the Court would need to reopen those deadlines. Further, Gore's amendment will cause Plaintiffs to incur additional legal costs that could have been prevented if the inequitable conduct claim was asserted in 2006. Therefore, the factor of prejudice to the opposing party, weighs against granting leave for Gore to amend its answer. See Jackson, 902 F.2d at 1387 (holding "prejudice to the opposing party is the most important factor" in the weighing test).

#### Bad Faith. 3.

Bad faith in filing a motion for leave to amend exists when the addition of new legal theories are baseless and presented for the purpose of prolonging the litigation. See Griggs v.

Pace American Group, Inc., 170 F.3d 877, 881 (9th Cir. 1999). The Court finds no evidence that the amendment is sought in bad faith. Thus, this factor weighs in Gore's favor.

#### 4. Futility.

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"Where the legal basis for a cause of action is tenuous, futility supports the refusal to grant leave to amend." Lockheed Martin Corp., 194 F.3d at 986. "A proposed amendment is futile if 'no set of facts can be proved under the amendment to the pleadings that would constitute a valid and sufficient claim or defense." Collaboration Properties, Inc., 2007 U.S. Dist. LEXIS 8632, at \*8.

Gore alleges facts that, if true, could support a claim for inequitable conduct. While neither party addresses the futility factor, it weighs in favor of granting leave to amend. While both the futility and bad faith factors do not weigh against granting leave to amend, the Court finds that Gore's delay, the delay that would be associated with conducting additional discovery, and the significant prejudice to Plaintiffs outweigh these factors.

### **CONCLUSION**

For the foregoing reasons, the Court hereby DENIES Defendant's motion for leave to file an amended answer.

### IT IS SO ORDERED.

Jeffuy & White

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United States District Court
For the Northern District of California

Dated: April 2, 2008			
	JEFFREY S. WHITE UNITED STATES DISTRICT JUDGE		
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